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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,701	07/30/2001	Terry Brady	4000-102-30CONT	8244

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SUPERVISOR PATENT PROSECUTION SERVICES
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EXAMINER	
WALLENHORST, MAUREEN	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,701	BRADY ET AL.	
	Examiner	Art Unit	
	Maureen M. Wallenhorst	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-20 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The disclosure is objected to because of the following informalities: On page 1 of the specification after the title of the invention in the section entitled "Cross-Reference to Related Applications", the following phrase should be inserted after the phrase "application number 08/933,181 filed September 18, 1997" so as to update the status of the parent application: --, now US Patent no. 6,410,337, issued on June 25, 2002, --.

Appropriate correction is required.

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In part b) of claim 1, the baseline count of the platelets is indefinite since it is not clear what this refers to. Does a baseline count refer to a number of platelets in the sample before any of the platelets are activated? See this same problem in part b) of claim 9. In part c) of claim 1, the phrase "the activatable platelets" lacks antecedent basis. See this same problem in part c) of claim 9. In part d) of claim 1, the phrases "the unactivated platelets" and "the active platelets" lack antecedent basis. See this same problem in part d) of claim 9. At the end of part d) in claim 1, the word –and—should be inserted since there is only one more step in the method to be recited. This same change should also be made in part d) of claim 9. In part e) of claim 1, the phrase "in the original sample" is indefinite since part a) of claim 1 recites two samples. Are the two samples recited in part a) taken from the same source comprising platelets to make up the original sample? In part e) of claim 9, the phrase "the original sample" should be changed to –the sample--.

Claim 2 is indefinite since it is not clear whether the "count of platelet" includes both the baseline count and the count of unactivated platelets recited in part d) of claim 1. See this same problem in claim 10.

In claim 4, the phrase "the second tube" lacks antecedent basis. See this same problem in claim 8.

On line 1 of claim 5, the phrase "the platelet activation agent" should be changed to –the platelet activation agonist—so as to use the same terminology as in claim 1. This same change should also be made on line 1 of claim 12.

In claim 11, the phrase "the tube" lacks antecedent basis.

In claim 15, the phrase "the second tube" lacks antecedent basis.

In claim 16, the word "optionally" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 6-14 of U.S. Patent No. 6,410,337. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method and a kit for measuring platelet function by the counting of platelets both before and after exogenous platelet activation by obtaining a baseline count of platelets in a first sample, mixing an activation agonist with a second sample for a period of time effective to maximally activate platelets in the second sample, obtaining a count of unactivated platelets in the second sample, and utilizing the different in the baseline count of platelets in the first sample from the count of unactivated platelets in the second sample as a measure of the activity of the platelets in the original source from which the first and second samples are taken.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 9-10 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryan.

Ryan teaches of a method for determining platelet aggregation by the counting of platelets before and after exogenous platelet activation. The method comprises the first step of collecting a blood sample containing platelets in an EDTA anticoagulant, and counting the number of platelets in the blood sample to obtain an initial platelet count to serve as a baseline. This platelet count serves as a baseline since the EDTA prevents any of the platelets from becoming activated. The next step in the method is to contact the sample with an activation agonist for a period of time effective to maximally activate the activatable platelets in the sample. The activation agonist comprises calcium chloride, sodium citrate and a platelet aggregating agent. The calcium chloride and sodium citrate work together to reverse the inactivating effect that EDTA has on platelets contained in the blood sample so that the platelet aggregating agent can cause the platelets to become activated. The platelet activating agent or agonist can be collagen, adenosine diphosphate (ADP), epinephrine, ristocetin, thrombin, etc. These agonists are used in amounts capable of inducing platelet aggregation. The next step in the method is to count the number of platelets in the blood sample which has been contacted with the combination of platelet agonist materials. The platelet aggregation is then calculated from the difference in the initial platelet count from the count of platelets after contact with the agonist materials, i.e. the equation:

Platelet aggregation=(initial platelet count-platelet count after contact with agonist materials)/initial platelet count.

The platelet counts are obtained using a conventional cell counter such as a Cell Dyn 900 platelet counter based upon measuring a change in impedance. In example 1 taught by Ryan, two samples containing platelets are collected in tubes. One tube contains the blood preservative

EDTA while one contains a citrate blood preservative. Collagen is then added to the tubes as a platelet activation agonist, and the platelets in each tube are counted. The count of platelets in the tube containing EDTA represents an initial baseline platelet count since the EDTA prevents any of the platelets from being activated while the count of platelets in the tube containing citrate represents a percentage of platelets which have been activated to aggregate. Therefore, in example 1, Ryan teaches of a kit comprising at least one tube comprising a platelet activation agonist (collagen) in an amount effective to maximally activate activatable platelets to be added to the tube and a blood preservative which does not substantially interfere with platelet function (citrate).

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-8, 11-15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan. For a teaching of Ryan, see previous paragraphs in this Office action.

Ryan fails to teach of utilizing two separate samples in the method, with one sample containing EDTA so as to prevent platelet activation in order to obtain the initial baseline count and one devoid of any agent which interferes with platelet function in order to obtain the number of platelets activated by the platelet agonist materials. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to utilize two separate samples of blood containing platelets in the method taught by Ryan, with one sample containing EDTA and one sample devoid of any agent which interferes with platelet function, since Ryan discloses an embodiment of a platelet aggregation assay using two sample tubes—one containing EDTA and one containing citrate as a blood preservative—and then measuring the platelet count in each tube after incubation with a platelet agonist material so as to give (1) a baseline platelet count with the EDTA-tube since EDTA prevents platelets from aggregating and (2) a platelet count after activation with the citrate-tube since citrate does not interfere with platelet function and aggregation.

Ryan also fails to teach of incorporating other known platelet agonist materials such as ADP into a tube used in the embodiment taught in Example 1. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate other known platelet activation agonists such as ADP into one of the tubes for testing platelet function taught by Ryan so as to evaluate the activity of many known platelet activation agonists on a given sample of blood at the same time in a convenient manner without any prior preparation of the reagents needed to perform the assays.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Lane et al, Baugh et al, Ostgaard et al, Reers, Varon et al, Baugh, Hemker et al and La Duca et al who all teach of different methods and devices for evaluating platelet function and aggregation.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

March 15, 2004

Maureen M. Wallenhorst
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